venaxis™

APPYReader™

User Manual

Copyright

This document discloses subject matter in which Venaxis, Inc. has certain proprietary rights. Neither receipt nor possession of this document confers or transfers any rights to reproduce, store in a retrieval system, transmit or translate in any form or by any means, electronic, mechanical, photocopying, recording or otherwise, without prior permission from Venaxis. The information contained in this User Manual is subject to change. Illustrations, including software screen illustrations, are representative, and may not reflect the most recently released updates.

Copyright © 2013 Venaxis, Inc. All rights reserved.

Venaxis, Inc.
1585 South Perry Street
Castle Rock, CO 80104
USA
www.venaxis.com
Tel: +1-303-794-2000
Fax: +1-303-798-8332

Emergo Europe
Molenstraat 15
2513 BH, The Hague,
The Netherlands

For U.S. Export Only

Distributor

To locate a distributor in your region, please visit Venaxis.com.

Table of Contents

1. HOW TO USE THIS MANUAL 5

2. READER OVERVIEW 5

2.1 Kit Components 6
2.2 Reader Front View 7
2.3 Reader Rear View 8
2.4 Understanding Screens and Menus 9
2.4.1 Header Bar 9
2.4.2 Content Area 10
2.4.3 Soft Key Selections 10
2.4.4 Selecting Menu Items 10
2.4.5 Entering Text 11
2.5 Understanding Labeling Symbols 12
2.6 Safety Symbols 13
2.7 Safety Information 13

3. SETTING UP THE READER 15

3.1 Supplying Power to the Reader 15
3.2 Using an Optional Barcode Scanner 15
3.3 Turning On the Reader 15
3.4 Setting or Changing the Date and Time 16
3.5 Adding the First Supervisor User and Additional Users 18
3.6 Changing Settings 22
3.7 Changing the Language 23
3.8 Changing Data Entry Method Settings 24
3.9 Changing the Print Setting 26
3.10 Changing Security and Power Saving Settings 27
3.11 Connecting to the LIS 29
3.11.1 Setting Up the Network Connection 29
3.11.2 Providing LIS Settings 31

4. DAILY OPERATIONS 33

4.1 Turning On the Reader 33
4.2 Logging In 33
4.3 Quality Control 34
4.3.1 Running the QC Cassette 35
4.3.2 Running Liquid Quality Control (QC) 37
4.4 Testing a Patient Sample 40
4.5 Managing Patient Results 44
4.5.1 Viewing Test Results in Reader Memory 44
4.5.2 Viewing a Result Stored on a Test Cassette 46

4.6 SHUTDOWN 47

5. REVIEW READER INFORMATION 48

5.1 CHECKING THE SOFTWARE VERSION 48
5.2 REVIEWING THE SUPERVISOR HISTORY 50
5.3 REVIEWING GLOBAL SETTINGS 51
5.4 DELETING STORED TEST RESULTS 54

6. MAINTAINING THE READER 56

6.1 CLEANING THE READER 56
6.2 CHANGING THE PAPER 56
6.3 REPLACING THE BATTERIES 59

7. TROUBLESHOOTING TIPS 61

7.1 UNDERSTANDING ERROR MESSAGES 62

8. SYSTEM SPECIFICATIONS 64

8.1 RETURNING THE READER 64
8.2 DISPOSING OF THE READER 65
8.3 ACCESSORIES AND PART NUMBERS 65

9. GLOSSARY 66

1. How To Use This Manual

The following conventions are used in this manual:

– Each screen is referenced by the name that appears at the top of the screen.

– Words on the screen (titles, on-screen options and soft key labels) are shown in bold.

– Buttons are referenced only by their icon.

For example: Use and to make the necessary changes.

– To make instructions easy to read, soft keys are referenced only by their label.

For example: Press **Select** to save this setting.

– Sections with blue text contain useful information that is relevant to chapter content or important usage information. For example:

IMPORTANT: To maintain the expected useful life of the QC cassette, avoid light exposure. Store and reseal the QC cassette in its original pouch immediately after each use.

2. Reader Overview

The *APPY*Reader™ Instrument (the reader) is a fluorescence instrument used to measure relative fluorescence units (RFU) generated by lateral flow immunoassay tests manufactured by Venaxis. The reader is designed for use in a laboratory setting.

Light from the reader's UV LED hits a test cassette once inserted into the reader. The UV light causes fluorescent dye in the test cassette to emit energy as relative fluorescence units (RFU). Based upon lot and analyte specific calibration coefficients programmed onto an RFID tag in each individual test cassette, the reader uses the measured RFU to calculate specific protein marker concentrations in a test sample. The concentrations of the two markers, in combination with White Blood Cell count (WBC) values obtained from a hospital's hematology analyzer and entered into the dedicated reader, are used to determine the patient's *APPY*1™ Test result according to a preprogrammed proprietary algorithm.

***APPY*Reader Instrument and *APPY*1 Test Cassette**

Each test cassette RFID chip identifies relevant parameters for evaluating the test results. These parameters include:

- Test name
- Assay specific calibration coefficients
- Expiration date

Patient information is entered in the reader either manually or using the optional barcode scanner.

The test cassette is placed in the reader's drawer with the sample application area facing toward the user. A patient test sample (processed plasma) is applied to the cassette sample application area and the drawer is closed to start the test. The reader reads the test cassette RFID chip and processes the test based on pre-programmed settings. The reader measures the level of protein markers, interprets, and reports the test result. Test results can be printed, sent to the LIS, or exported to an optional SD card.

2.1 Kit Components

The following components are included in the *APPY*Reader Kit:

- *Reader*
- Universal Power Transformer
- Power Cord
- Plug Adapter
- AA Batteries (4)
- QC Cassette
- Thermal Paper Rolls (2)
- User Manual (CD)
- Warranty Card
- Start-Up Guide

NOTE: To order consumables, accessories or replacement parts for your reader, contact your local distributor or Venaxis Technical Support.

Front View

2.2 Reader Front View

1 Printer Cover	Covers the printer.
2 Display	Shows screens for navigating, entering data and reviewing data.
3 Eject Button	Used to eject the drawer.
4 Paper Feed Button	Used to advance the paper roll.
5 Main Menu Button	Used to return to the **Main Menu** screen.
6 Left Soft Key	Used to select the option shown above the key on the display.
7 Navigation Buttons	Used to navigate within menus and reader screens.
8 Right Soft Key	Used to select the option shown above the key on the display.
9 Numeric Keypad	Used to enter numbers and decimal points.
10 Delete Button	Used to delete the character to the left of the cursor.
11 Battery Cover	Covers the battery compartment.
12 Drawer	Used to insert prepared test and QC cassettes in the reader.

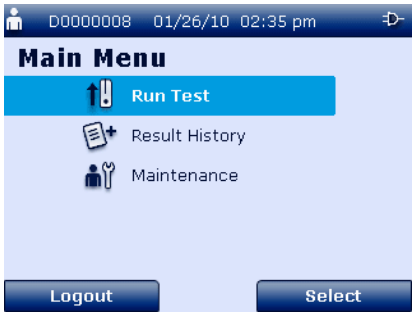
Reader Back View

2.3 Reader Rear View

1 PS/2 Port	Used to connect the optional barcode scanner accessory to the reader.
2 Ethernet Port	Used to connect the reader to the LIS network.
3 AC Power Port	Used to connect the AC power adapter to the reader.
4 SD Card Slot	Used for importing and exporting information via the SD card.
5 On/Off Switch	Used to turn the reader on and off.

2.4 Understanding Screens and Menus

Each screen is divided into three areas: the header bar, the content area, and the soft keys.



Main Menu Screen

The information displayed in each area is described below.

2.4.1 Header Bar

The dark blue bar at the top of the screen that provides the following information:

- The icon at the far left indicates whether the user is logged in as a supervisor or an operator.
- The number next to the user icon is the current operator ID. If the auto-login setting is enabled, the header bar shows “Auto-Login” instead of the operator ID.
- The date and time are shown to the right of the user information.
- The icon shown at the far right indicates whether the reader is using AC or battery power.

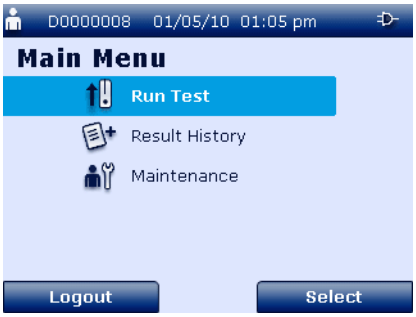
This Icon…	indicates that…
	The user is logged in as a supervisor.
	The user is logged in as an operator.
	The reader is using battery power and the batteries are fully charged. The battery icon is gradually filled with white as the battery life is depleted.
	The AC power adapter is being used to power the reader.

2.4.2 Content Area

The content area is the light blue area occupying the majority of the reader screen. This area displays menu options, settings and data.

When you are logged in as a supervisor, the selected option is indicated by a yellow bar with black text. When you are logged in as an operator, the selected option is indicated by a blue bar with white text.

Supervisor Main Menu Screen



Operator Main Menu Screen

2.4.3 Soft Key Selections

The soft key selections are the dark blue areas with white text displayed at the lower left and lower right of the reader screen. Some screens have two soft key selections, while other screens have only one option.

To use a soft key selection, press the soft key below the desired option.

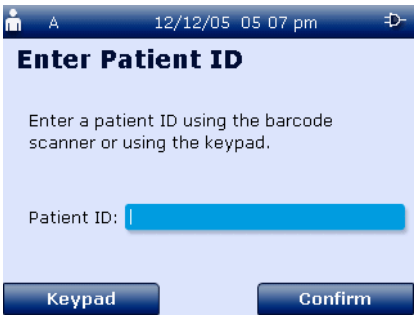
2.4.4 Selecting Menu Items

Use navigation keys and to highlight the field. Press the right soft key to select the item.
Use radio buttons to indicate the selected feature.

Set Language Screen

2.4.5 Entering Text

Text can be entered for patient IDs, supervisor IDs, operator IDs and quality control lot numbers. Numbers can be intermixed with letters at any time by using the numeric keypad. The text entry screen is automatically shown when entering supervisor and operator IDs.



Push the **Keypad** soft key to bring up the text entry screen when entering patient IDs and quality control lot numbers.

a. Use , , , and to highlight the desired character.

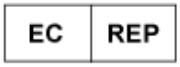
b. Press **Confirm & Next** to add the highlighted character to the user name.

c. Repeat **Step a** and **Step b** as necessary.

d. When the name is complete, use , , , and to highlight Done. Select **Confirm & Next.**

2.5 Understanding Labeling Symbols

The following symbols are located on the bottom of the reader:

This symbol...	indicates...
	CE Mark
	Consult Instructions for Use
	For *In Vitro* Diagnostic Use
	Catalog Number
	Humidity Limitation
	Temperature Limitation
	Federal Communication Commission (U.S.)
	Authorized Representative in the European Community
	The device requires safe disposal in conformance with the WEEE Directive, 2012/19/EU
	The polarity of the power supply tip is positive.
	Manufacturer
	Class 1M UV LED Product. Do not view directly with optical instruments.

2.6 Safety Symbols

The following symbols are used in this User Manual:

This Icon…	indicates that…
	BIOHAZARD WARNING: A situation, which if not avoided, could result in a health risk to the user.
	ELECTRICAL SHOCK WARNING: A situation, which if not avoided, could result in electrical damage to the reader or bodily injury to the user.
	CAUTION OR WARNING: A situation, which if not avoided, could result in incorrect operation or damage to the reader.

2.7 Safety Information

Review the safety information below before using the reader.

	CAUTION: Use the reader only in the operating environment specified. For details, see ***Product Specifications***.
	CAUTION: To ensure proper operating temperature, do not place the reader near radiators, bright sunlight, heat registers, stoves, or other heat-producing equipment.
	WARNING: Operate the reader using only the power cord and power supply (AC adaptor) provided. Connect the reader to an earth-grounded outlet that meets the product's power specifications. For details, see ***Product Specifications***.
	WARNING: The reader is intended for indoor use only. To reduce the risk of electrical shock, always unplug the power supply from the AC power source following use.

CAUTION: Results are stored in the reader memory for temporary backup purposes only and may be overwritten. The reader memory stores results for up to 500 patient test results. When memory capacity is reached, the most recent result automatically overwrites the oldest result.

WARNING: When using the reader, observe universal safety and laboratory precautions, and follow laboratory operating procedures regarding personal protective equipment (i.e. lab coats, gloves) and safety.

WARNING: Handle and dispose of test cassettes in accordance with standard biohazard practices.

WARNING: Do not remove external panels to access the interior of the reader. The reader contains a Class 1M UV LED used to illuminate the test cassettes. Class 1M UV LEDs are not considered to be hazardous when used as intended.

3. Setting Up The Reader

3.1 Supplying Power to the Reader

Connect the AC power adapter that was supplied with the reader as follows:

1. Connect the AC power adapter to a power outlet.

Connecting the AC Power Adapter

2. Insert the cylindrical end of the AC adapter into the back of the reader.

IMPORTANT: Use of any other AC adapter than the supplied power adapter may void the reader warranty.

3.2 Using an Optional Barcode Scanner

A barcode scanner with a PS/2 interface can be used for entering data. To use an optional barcode scanner, plug the end of the barcode scanner cable into the PS/2 port in the back of the reader.

3.3 Turning On the Reader

The on/off switch is located on the back of the reader. To turn on the reader, push the on/off switch until the **Initializing** screen appears, then release it. The reader displays a splash screen during startup then displays the **Set Date** screen. Date and time must be set before running any quality control or patient samples.

Set Date Screen

IMPORTANT: Allow the reader to warm up for at least 10 minutes before running any patient samples.

3.4 Setting or Changing the Date and Time

Perform the following steps to set or change the date and time:

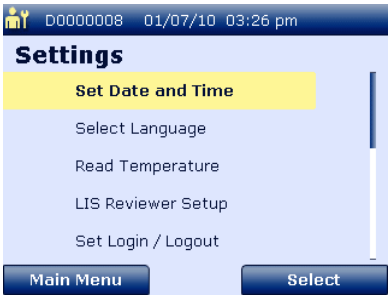
1. *To **set** date and time*, when the **Set Date** screen is first displayed, the **Date Format** field is highlighted. (Skip to Step #5)
2. *To **change** date and time*, press to display the supervisor **Main Menu** screen.

Supervisor Main Menu Screen

IMPORTANT: You must add the first supervisor user before you can change any reader settings. See Adding the First Supervisor User.

NOTE: Only supervisor users can use this feature. If you are logged in as an operator, select Maintenance > Change to Supervisor.

3. Use and to highlight **Settings** and press **Select**.



Supervisor Settings Screen

4. Use and to highlight **Set Date** and **Time** and press **Select**.

Set Date Screen

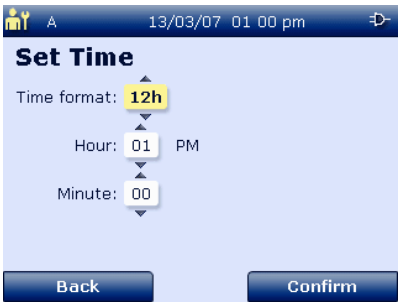
5. Use and to scroll through the following screen and printout date format options:

   - **dd.mm.yyyy:** Select this option to display the day, then the month, then the year with periods used as separators.
   - **mm/dd/yyyy:** Select this option to display the month, then the day, then the year with slashes used as separators.
   - **yyyy/mm/dd:** Select this option to display the year, then the month, then the day with slashes used as separators.

   When the preferred date format is displayed, press to highlight the **Year** field.

6. To set the year, month and day use and to highlight the respective field. Use and to change the setting.

7. When you have confirmed that the correct date is displayed, press **Confirm & Next**.



Set Time Screen

8. Use ▲ and ▼ to toggle between the following screen and printout time format options:

   - **12h:** Select this option to display times in the 12-hour time format with a.m. and p.m.
   - **24h:** Select this option to display times in the 24-hour time format.

   When the preferred time format is displayed, press ▶ to highlight the **Hour** field.

9. To set the hour and minute use ◀ and ▶ to highlight the respective field. Use ▲ and ▼ to change the setting.
10. When the correct time is displayed, press **Confirm** to accept all settings.
11. If the reader has been allowed to warm up for 10 minutes, you may begin running quality controls and patient samples. See ***Testing a Patient Sample*** for instructions.

3.5 Adding the First Supervisor User and Additional Users

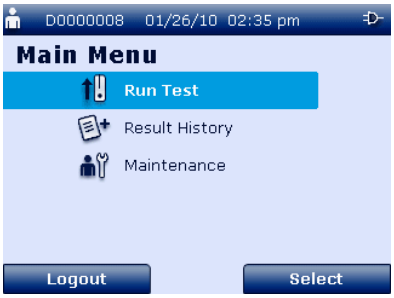
IMPORTANT: You must add the first supervisor user before you can change any reader settings. In order to add the first supervisor user, you need to obtain a one-time PIN by calling Venaxis Customer Care at 1-877-276-1976 or +1-303-794-2000.

IMPORTANT: A one-time PIN can be used only on the day when it is provided. You should add the first supervisor user as soon as you obtain this PIN.

.

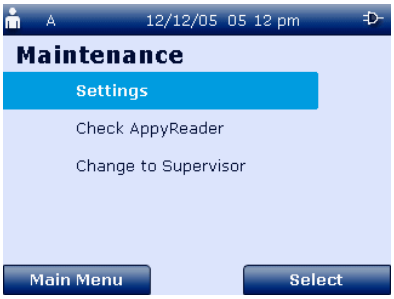
With the one-time PIN, perform the following steps to create the first supervisor user:

1. Press to display the operator Main Menu screen.



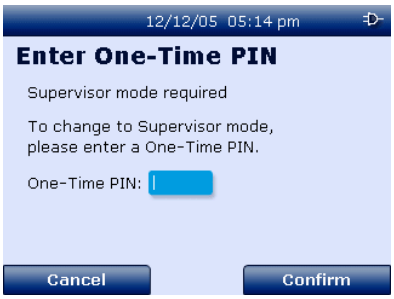
Operator Main Menu Screen

2. Select **Maintenance**.



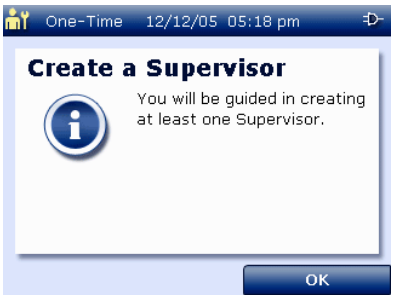
Maintenance Screen

3. Select **Change to Supervisor**.



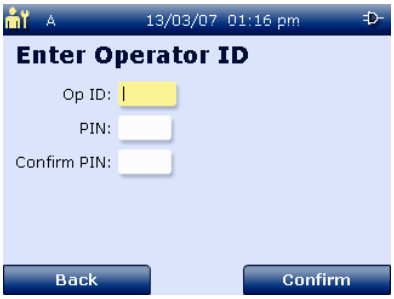
Enter One-Time PIN Screen

4. Use the numeric keypad to enter your one-time PIN in the **One-Time PIN** field. Press **Confirm**.



Create a Supervisor Confirmation Screen

5. Press **OK**.



Enter Operator ID Screen

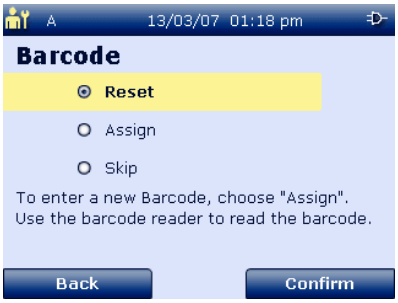
6. Use the numeric keypad to enter the ID for the first supervisor. The ID must be 4 digits.

NOTE: To delete the last character entered, press ⇦.

7. Use the numeric keypad to enter the user PIN. The PIN must be 4 digits.
8. Use the numeric keypad to confirm the user PIN.
9. Press **Confirm & Next**.

Enter User Name Screen

10. Enter the user name.
11. Use ▲, ▼, ◀ and ▶ to highlight **Done**. Then press **Confirm & Next**.



Barcode Screen

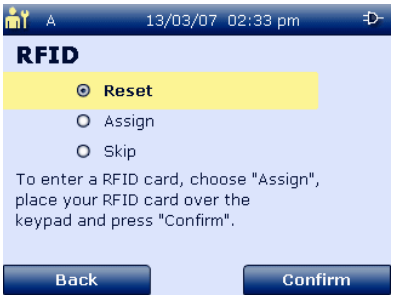
12. The following options are available on the Barcode screen:

    a. *To assign a barcode for this user,* use ▲ and ▼ to highlight **Assign**, then use the external barcode scanner to scan the barcode.

    The reader assigns the barcode and displays the **RFID** screen.

NOTE: To delete this user's barcode, return to the Barcode screen and use ▲ and ▼ to highlight *Reset*. Then press *Confirm* & *Next*.

    b. *If you do not want to assign a barcode,* use ▲ and ▼ to highlight Skip. Then press **Confirm & Next**.



RFID Screen

13. *If the facility uses RFID cards for laboratory personnel,* the reader can be programmed to read the facility-supplied RFID card. The following options are available on the **RFID Screen**:

NOTE: The facility-supplied RFID card must comply with ISO/IEC 15693.

    a. *To assign an **RFID** for this user*, use ▲ and ▼ to highlight **Assign**. Hold the user's RFID card over the reader keypad then press **Confirm**.

    The reader assigns the RFID and displays the **Operator Administration** screen.

    b. *If you do not want to assign an **RFID***, use ▲ and ▼ to highlight **Skip**. Then press **Confirm**.

NOTE: To delete this user's RFID, return to the RFID screen and use and to highlight *Reset*. Then press *Confirm*.

14. After adding the first supervisor, you can change reader settings, add more users or set up the LIS connection. Refer to the appropriate section below for instructions:

    - ***Changing Reader Settings***
    - ***Managing Users***
    - ***Connecting to the LIS***

Supervisor users can modify the following reader settings:

- **Language:** The language setting determines what language is displayed on the reader screen and printouts. To change, see ***Changing the Language***.
- **Data Entry Method**: The data entry method settings determine whether data can be entered using a barcode scanner and whether they can be entered manually. To change, see ***Changing Data Entry Method Settings***.
- **Print Setting:** The print setting determines whether test results are printed automatically upon completion of a patient test. To change, see ***Changing the Print Setting***.
- **Logout Time:** The logout time setting is the duration of inactivity after which a user will be automatically logged out of the reader. To change, see ***Changing Security and Power Saving Settings***.
- **Power Off Time:** The power off time is the duration of inactivity after which the reader will automatically turn off. To change, see ***Changing Security and Power Saving Settings***.
- **Auto-Login Setting:** The auto-login setting determines whether users are required to enter a login and PIN to use the reader. To change, see ***Changing Security and Power Saving Settings***.

NOTE: Only supervisor users can change reader settings. If you are logged in as an operator, select Maintenance > Change to Supervisor to change settings.

3.6 Changing Settings

Supervisor users can change the reader's settings. Settings are changed from the **Settings** screen.

Perform the following steps to get to the **Settings** screen:

1. Press to display the supervisor **Main Menu** screen.

Supervisor Main Menu Screen

2. Use and to highlight **Settings** and press **Select**.

Settings Screen

3.7 Changing the Language

Supervisor users can change the reader's language setting. The language setting determines what language is displayed on the reader screen and printouts.

Perform the following steps to change the language:

1. Go to the **Settings** screen.

Supervisor Settings Screen

2. Use and to highlight **Select Language** and press **Select**.
3. Use and to highlight the desired language.
4. When the desired language is highlighted, press **Select** to save this setting.
5. Press **Back** to return to the supervisor **Settings** screen or press to return to the supervisor **Main Menu** screen.

3.8 Changing Data Entry Method Settings

Supervisor users can change data entry method settings. The data entry method settings determine whether data can be input by an external barcode scanner and whether they can be input by manual entry.

Perform the following steps to change data entry method settings:

1. Go to the **Settings** screen.
2. Use and to highlight **Data Entry Method** and press **Select**.

Data Entry Method Screen

3. Perform the following steps to enable or disable use of the barcode scanner for data entry (such as patient ID, LQC ranges):
   a. Use and to highlight **Set Barcode Scanner** and press **Select**

The selected radio button indicates the current setting.

Set Barcode Scanner Screen

b. Use and to highlight the desired setting.

- If you select **Enabled**, a barcode scanner can be used to enter data.
- If you select **Disabled**, a barcode scanner cannot be used to enter data.

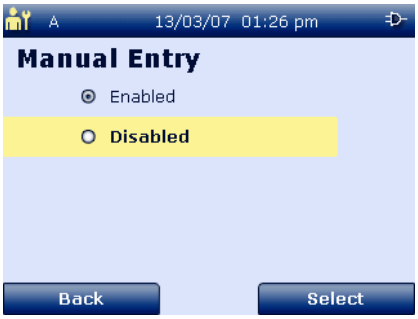
c. When the desired setting is highlighted, press **Select** to save this setting.

d. Press **Back** to return to the **Data Entry Method** screen.

4. Perform the following steps to enable or disable manual entry of the data:

a. Use and to highlight **Manual Data Entry** and press **Select**.

The selected radio button indicates the current setting.



Allow Manual Entry Screen

b. Use and to highlight the desired setting.

- If you select **Enabled**, data can be entered using the keypad.
- If you select **Disabled**, data cannot be entered manually.

c. When the desired setting is highlighted, press **Select** to save this setting.

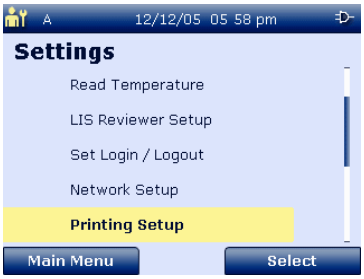
d. Press **Back** to return to the **Data Entry Method** screen or press to return to the supervisor **Main Menu** screen.

3.9 Changing the Print Setting

Supervisor users can change the print setting. The print setting determines whether test results are printed automatically upon completion of a patient test.

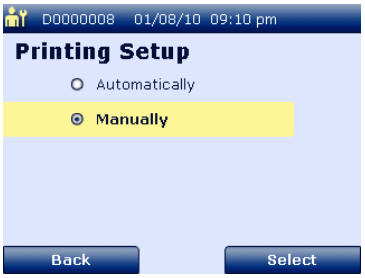
Perform the following steps to change the patient ID settings:

1. Go to the **Settings** screen.
2. Use and to highlight **Printing Setup** and press **Select**.



Supervisor Settings Screen

3. Use and to highlight the desired setting.



Printing Setup Screen

- *If you select **Automatically***, test results will be printed automatically upon completion of a patient test.
- *If you select **Manually***, test results will not be printed automatically upon completion of a patient test. Results will have to be printed manually by the user.

4. When the desired setting is highlighted, press **Select** to save this setting.
5. Press **Back** to return to the supervisor **Settings** screen or press to return to the supervisor **Main Menu** screen.

3.10 Changing Security and Power Saving Settings

Supervisor users can change the following security and power saving settings:

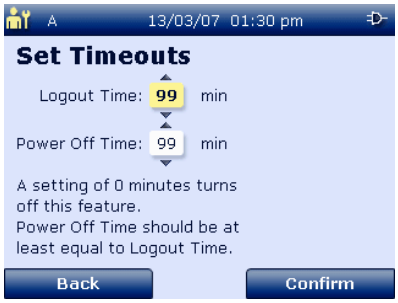
- **Logout Time:** The logout time setting is the duration of inactivity after which a user will be automatically logged out of the reader.
- **Power Off Time:** The power off time is the duration of inactivity after which the reader will automatically turn off.
- **Auto-Login Setting:** The auto-login setting determines whether users are required to enter a login and PIN to use the reader.

Perform the following steps to change the logout time, power off time, or auto-login setting:

1. Go to the **Settings** screen
2. Use and to highlight **Set Login / Logout** and press **Select**.

Set Login / Logout Screen

3. Perform the following steps to change the logout time and/or power off time:
   a. Use and to highlight **Set Timeouts** and press **Select**.


A
13/03/07 01:30 pm
Set Timeouts
Logout Time: 99 min
Power Off Time: 99 min
A setting of 0 minutes turns off this feature.
Power Off Time should be at least equal to Logout Time.
Back
Confirm

Set Timeouts Screen

When the **Set Timeouts** screen is first displayed, **the Logout Time** field is highlighted. If necessary, use and to increase or decrease the logout time.

NOTE: Select a logout time of 0 minutes if you never want users to be automatically logged out of the reader.

b. When the desired logout time is displayed, press to highlight the **Power Off Time** field.

NOTE: Select a power off time of 0 minutes if you never want the reader to automatically turn off.

c. If necessary, use and to increase or decrease the power off time.

d. When the desired power off time is displayed, press **Confirm** to save these settings.

4. Perform the following steps to change the auto-login setting:

a. On the **Set Login / Logout** screen, use and to highlight **Set Auto-Login** and press **Select**.

Set Auto-Login Screen

b. Use and to highlight the desired setting.

   – *If you select **Enabled***, users will not be required to enter a login and PIN to use the reader.

   – *If you select **Disabled***, users will be required to enter a login and PIN to use the reader.

c. When the desired setting is highlighted, press **Select** to save this setting.

d. Press **Back** to return to the **Set Login / Logout** screen.

3.11 Connecting to the LIS

The reader can send test results to the LIS over an Ethernet connection. Complete the following steps to set up the LIS connection.

3.11.1 Setting Up the Network Connection

Perform the following steps to set up the network connection. If you are not using DHCP, you need to obtain the IP address, port number, subnet mask, and standard gateway for the reader from your network administrator.

1. Connect an Ethernet cable to the reader by inserting one end of the cable into the Ethernet port in the back of the reader.

Connecting the Ethernet Cable

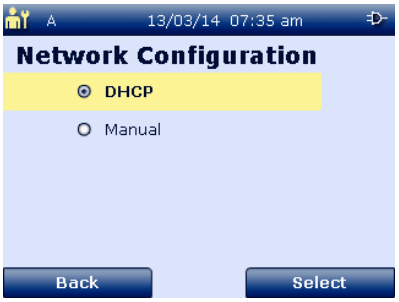
2. Connect the other end of the Ethernet cable to the LIS network.

3. Go to the **Settings** screen.

4. Use and to highlight **Network Setup** and press **Select** to display the **Network Setup** screen.

Network Setup Screen

5. Use and to highlight **Network Configuration** and press **Select**.



Network Configuration Screen

6. The following options are available on the **Network Configuration** screen:

   - *To obtain the reader's IP address, port number, subnet mask, and standard gateway automatically using DHCP*, use and to *highlight* **DHCP**. Then press **Select**.

     The reader obtains the network information and displays the **Network Setup** screen.

   - *To enter the reader's IP address, port number, subnet mask, and standard gateway manually*, use and to highlight **Manual**. Then press **Select**.

     a. When the **Manual Network Setup** screen is first displayed, the **IP address** field is highlighted. Use the numeric keypad to enter the IP address for the reader. Then press to highlight the **Port number** field.

NOTE: To delete the last character entered, press .

b. Use the numeric keypad to enter the port number for the reader. Then press to highlight the **Subnet Mask** field.

c. Use the numeric keypad to enter the subnet mask for the reader. Then press to highlight the **Standard Gateway** field.

d. Use the numeric keypad to enter the standard gateway for the reader.

Review the IP address, port number, subnet mask, and standard gateway and confirm that the correct information is displayed. If you need to change a setting, use and to highlight the field, then use the numeric keypad to make the necessary changes.

e. Press **Confirm** to save these settings and return to the **Network Setup** screen.

3.11.2 Providing LIS Settings

Perform the following steps to configure the LIS reviewer settings for the reader. You need to obtain the IP address and port number for the LIS reviewer from your network administrator.

1. Go to the **Settings** screen.

2. Use and to highlight **LIS Reviewer Setup** and press **Select**.

Supervisor Settings Screen

3. When the **LIS Reviewer Settings** screen is first displayed, the **Set Timeout** field is highlighted. Use and to increase or decrease the timeout for the LIS reviewer. The timeout is the amount of time after which the reader will stop trying to communicate with the LIS.

4. When the desired setting is displayed in the **Set Timeout** field, press to highlight the **Reviewer IP Address** field.

5. Use and to increase or decrease the IP address for the LIS reviewer. Then press to highlight the **Port Number** field.

6. Use and to increase or decrease the port number for the LIS reviewer.

7. Review the timeout, IP address, and port number and confirm that the correct information is displayed. If you need to change a setting, use and to highlight the field. Then use and to make the necessary changes.

8. Press **Confirm & Exit** to return to the supervisor **Settings** screen.

4. Daily Operations

This section provides information on preparing the reader for testing. The following tasks must be completed prior to testing patient samples:

- The reader must be powered on.
- A user must log in to the reader (unless the reader's auto-login feature is enabled).
- Quality control must be performed as required by laboratory procedures.

4.1 Turning On the Reader

The on/off switch is located on the back of the reader. To turn on the reader, push the on/off switch until the **Initializing** screen appears, then release it. The reader displays a splash screen during startup then displays one of the following screens:

- The **Login** screen is displayed if the reader's auto-login feature is disabled.
- The **Enter Patient ID** screen is displayed if the reader's auto-login feature is enabled.

IMPORTANT: Allow the reader to warm up for at least 10 minutes before running any patient samples.

4.2 Logging In

If necessary, perform the following steps to log in to the reader:

1. On the Login screen, enter your 4-digit user ID or barcode using one of the following methods:
   - Use the numeric keypad to enter your user ID manually.
   - Use the optional external barcode scanner to scan your barcode.
   - Place your facility-supplied RFID card over the reader keypad. Go to Step 4.

NOTE: Press the back space key ⇦ to delete the last character entered.

Login Screen

2. Press to highlight the **PIN** field.

3. Enter your 4-digit PIN.

4. Press **Login** to log in as an operator

NOTE: You can also press Supervisor Login to log in as a supervisor. If you log in as a supervisor, you will need to select Change to Operator to test patient samples.

4.3 Quality Control

Quality control (QC) testing ensures that the reader is operating within acceptable ranges. QC routines are mandatory and patient tests should not be performed unless required QC is complete. Refer to the *APPY*1 Control Kit Instructions for Use for additional information.

The reader performs initialization and self-checks each time it is powered on. These checks ensure that:

- Communication between the different reader modules is working.
- Reader settings and calibration integrity are verified.
- The optics are functioning properly.
- The carriage is free to move correctly.
- The carriage position is zeroed.

IMPORTANT: ***On each day of testing, the reader should be powered on and allowed to complete its initialization and self-checks.***

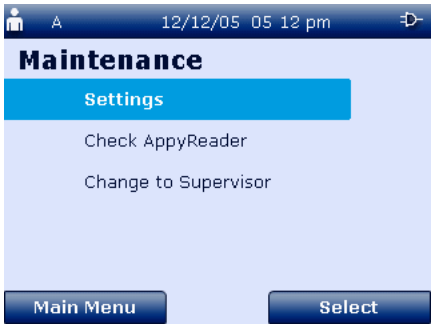
From the **Check *APPY*Reader** screen, you can run the QC cassette (QCC) provided with the reader. You can also run liquid QC (LQC). The test result can be printed or sent to the LIS.

IMPORTANT: Follow laboratory procedures regarding how frequently to perform QC checks and how to document the results.

NOTE: To send QC results to the LIS, the reader must be connected to the LIS and the LIS must have been set up by a supervisor. See Connecting to the LIS.

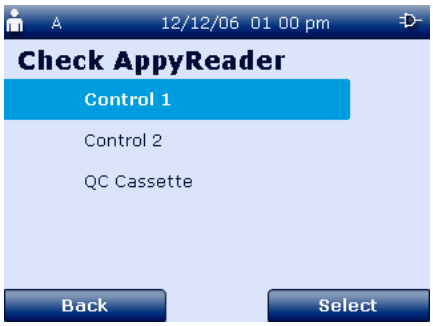
4.3.1 Running the QC Cassette

1. If you are logged in as a supervisor, go to the Main Menu and change to operator.
2. From the Mai**n Menu** highlight **Maintenance** and press **Select**.



Maintenance Screen

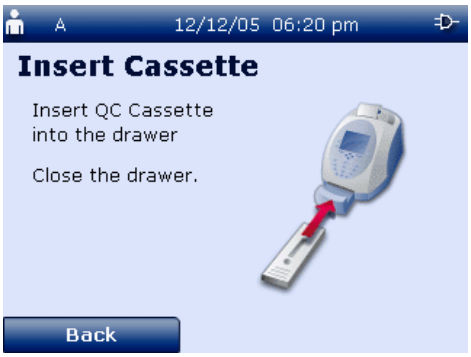
3. Use and to highlight **Check Reader** and press **Select**.



Check *APPY*Reader Screen

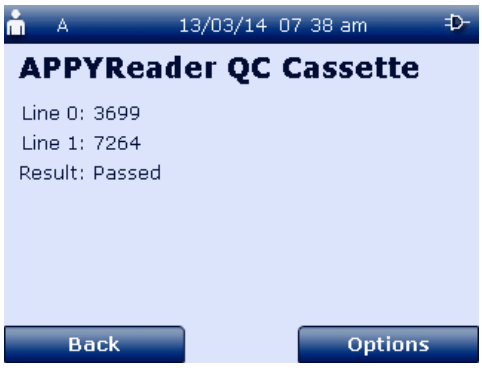
4. Use and to highlight **QC Cassette** and press **Select**.

5. The reader drawer will open and the **Insert Cassette** screen will be displayed.



Insert QC Cassette Screen

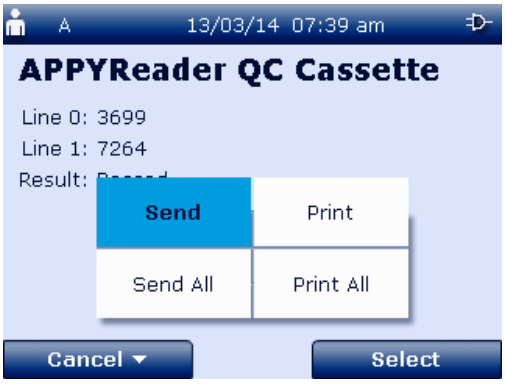
6. The ***APPY*Reader QC Cassette** screen is displayed when the test finishes.



***APPY*Reader QC Cassette Result Screen**

7. QC cassette result options:

   a. Press **Options**.



***APPY*Reader QC Cassette Options Screen**

   b. To print the result, Use and to highlight **Print Result** and press **Select**.

c. To print all the QC cassette results stored in the reader, highlight **Print All** and press **Select**

d. To send the result to a LIS system, highlight **Send Result** and press **Select**

QC Cassette Result Sending to LIS Screen

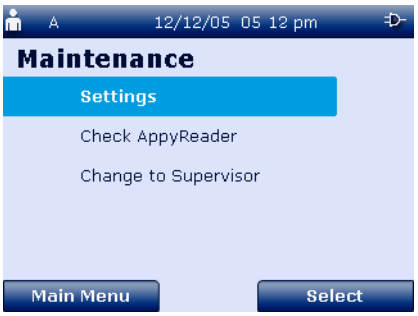
e. To send all the QC cassette results to a LIS system, highlight **Send All** and press **Select**

IMPORTANT: The QC cassette is REUSABLE and should NOT be discarded until the end of its useful life. Avoid light exposure and reseal and store the QC cassette in its original pouch immediately after each use.

4.3.2 Running Liquid Quality Control (QC)

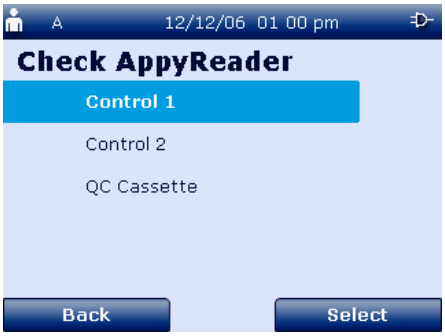
IMPORTANT: Allow the reader to warm up for at least 10 minutes before running any QC samples.

1. If you are logged in as a supervisor, go to the **Main Menu** and change to operator
2. From the operator **Main Menu** highlight **Maintenance** and press **Select**.



Maintenance Screen

3. Use and to highlight **Check APPYReader** and press **Select**.



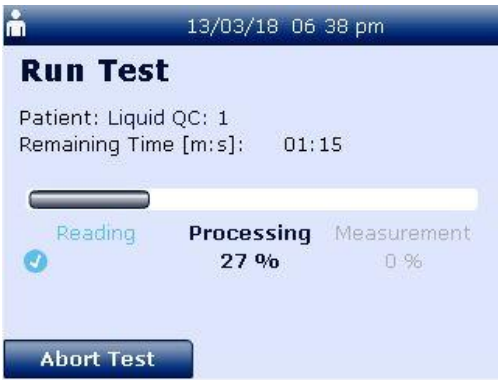
Check *APPY*Reader Screen

4. Use and to highlight **Control 1** or **Control 2** and press **Select**.

Insert Cassette Screen - Liquid Control

5. Remove the test cassette from its pouch and place it into the cassette drawer.
6. Prepare the control sample in accordance with the *APPY*1 Control Kit Instructions for Use and apply the sample to the test cassette port.

7. Gently close the drawer. The test will start automatically.

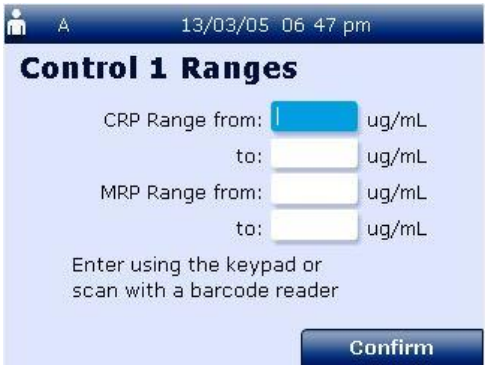


Liquid Control Testing Screen

8. You will be prompted to enter the QC lot number after the test completes in about 11 minutes**.**

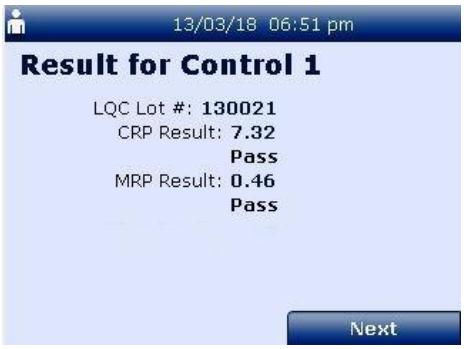
Enter Control Lot # Screen

9. Use the keypad or optional barcode scanner to enter the QC lot number and press **Confirm**.



Enter Control Ranges Screen

10. Use the keypad or optional barcode scanner to enter the QC ranges and press **Confirm.**



Control Result Screen

11. Press **Next** to return to the **Check APPYReader** screen.

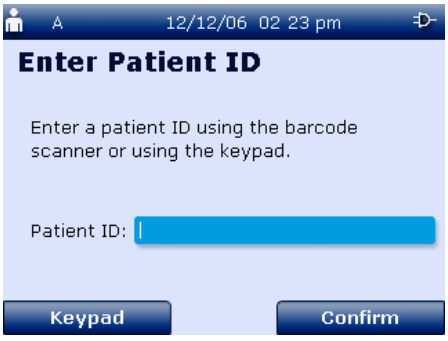
12. Press ⏏ to eject the drawer. Remove the test cassette and dispose or store as appropriate.

4.4 Testing a Patient Sample

> ⚠ **IMPORTANT: Allow the reader to warm up for at least 10 minutes before running any patient samples.**

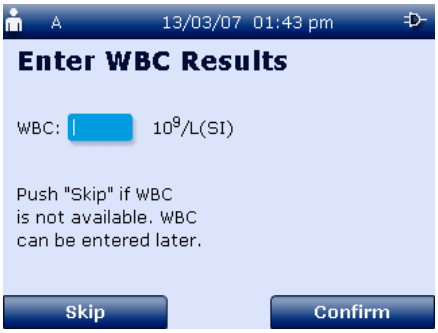
Perform the following steps to test a patient sample:

1. From the operator **Main Menu**, Use ▲ and ▼ to highlight **Run Test** and press **Select**.



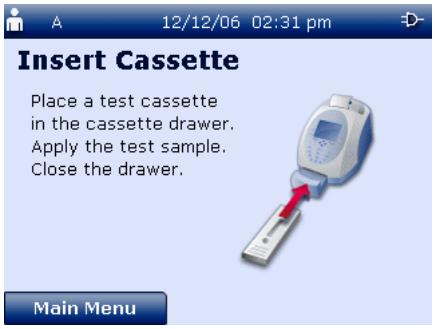
Enter Patient ID Screen

2. Enter the patient ID using one of the following methods:
    a. *To enter **manually***, press **Keypad**.
    b. *To use a **barcode scanner***, scan the patient ID.
3. Press **Confirm**.



Enter WBC Result Screen

4. If the patient WBC result is available, enter it and press **Confirm**. Otherwise press **Skip**. If you press **Skip**, you will be asked to enter the patient WBC after the test.

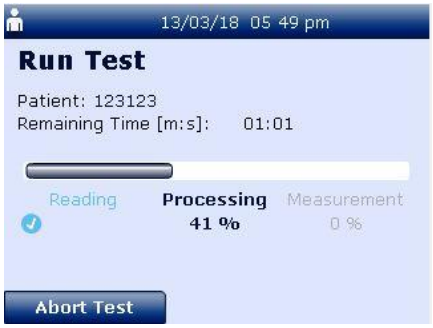


Insert Cassette Screen - Run Test

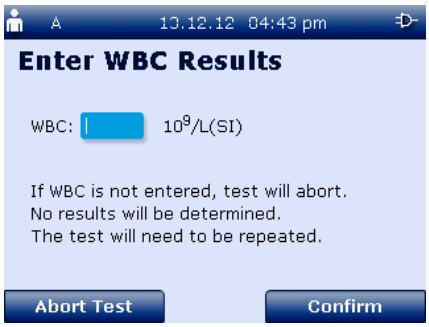
5. Remove the test cassette from its pouch and place it into the cassette drawer.
6. Prepare the sample in accordance with the *APPY*1 Test Kit Instructions for Use and apply the sample to the test cassette port.
7. Gently close the drawer. The test will start automatically.

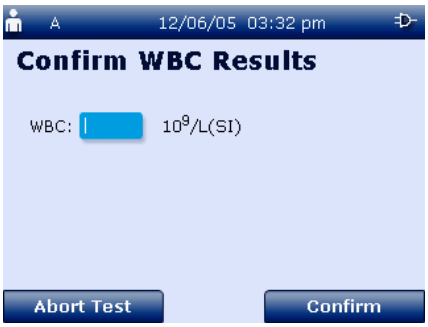
Test Cassette in Reader Drawer

8. The reader displays the status of the test on the **Run Test** screen.



9. When the test is done, you will be asked to enter the WBC or to confirm the WBC entered prior to the test.





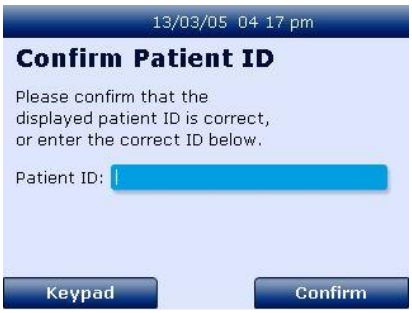
IMPORTANT: WBC must be confirmed within 90 minutes or the test is automatically aborted.

10. Re-enter the patient WBC and press **Confirm**.

Test Result Screen

IMPORTANT: The test cassette must remain in the reader until the Patient ID is confirmed.

11. Press **Next**, and the following screen will appear.



Confirm Patient ID Screen

12. To confirm that the entered patient ID is correct, on the above screen you must do one of the following:

    - *If the displayed patient ID is correct*, press **Confirm** to view the test result on the **Result List** screen. If the reader's automatic printing feature is enabled, the result is printed automatically.

Result List Screen

    - *If the displayed patient ID is incorrect:*

        a. Enter the correct patient ID and press **Confirm** to display the **Patient ID does not match** screen.

Patient ID Does Not Match Screen

        b. Review the displayed patient IDs, and re-enter the correct patient ID. Press **Confirm** to view the test result on the **Result List** screen.

13. Press ⏏ to eject the drawer. Remove the test cassette and dispose or store as appropriate.

4.5 Managing Patient Results

The **Result List** screen displays basic information for each patient test result stored in the reader's memory. From the **Result List** screen you can:

- view details for a patient test result
- send patient test results to the LIS
- print patient test results

You can also view, send, and print an individual result stored on a test cassette.

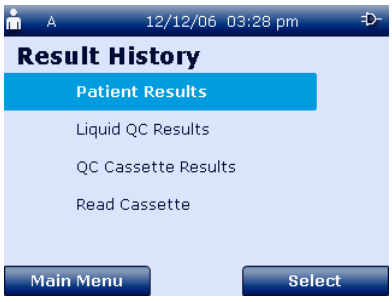
NOTE: To send a patient result to the LIS, the reader must be connected to the LIS and the LIS must have been set up by a supervisor. See Connecting to the LIS for instructions.

IMPORTANT: The reader can store up to 500 patient test results. When the reader's memory is full, a warning message is displayed prompting user action. If no action is taken, results are overwritten as new tests are completed, starting with the oldest result in memory.

4.5.1 Viewing Test Results in Reader Memory

Perform the following steps to view detailed information for test results stored in the reader's memory:

1. From the operator **Main Menu**, highlight **Result History** and press **Select**.



Result History Screen

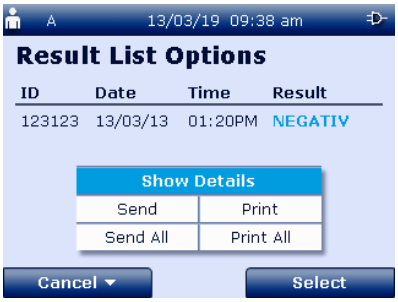
NOTE: The Result History menu item is not available on the supervisor Main Menu screen. If you are logged in as a supervisor, select Change to Operator.

2. Highlight **Organize Results** and press **Select**.

   The reader displays the patient ID, date, time, and test result for results in the reader's memory, starting with the most recent test. Scroll through results using and .

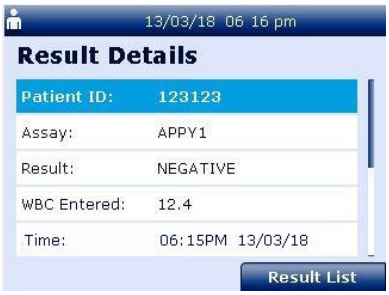
Result List Screen

3. Use and to highlight the desired result and press **Options ▲** to display the **Result List Options** screen.



Result List Options Screen

   a. To see the result details, highlight **Show Details** and press **Select**



Detailed Result Screen

The following information is available on the **Detailed Result** screen:

- **Patient ID:** The complete patient ID recorded for the test.
- **Assay:** The assay type that was performed (*APPY*1).
- **Result:** The result of the *APPY*1 Test.
- **WBC Entered:** The entered WBC count.
- **Time:** The time and date the test was performed.
- **Lot #:** The lot number of the cassette used for the test.
- **Op ID:** The ID for the operator that performed the test.
- **Last LQC:** The date of the last liquid QC performed on the reader.

When you have finished viewing result details, press **Back**.

b. To print the result, highlight **Print Result** and press **Select**.

c. To print all the test results stored in the reader, highlight **Print All** and press **Select**

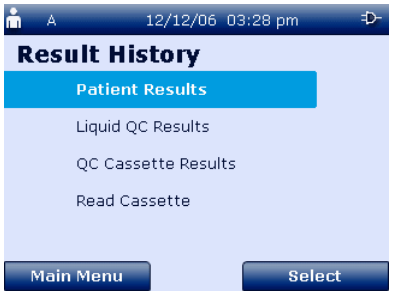
d. To send the result to a LIS system, highlight **Send Result** and press **Select**

e. To send all the test results to a LIS system, highlight **Send All** and press **Select**

4.5.2 Viewing a Result Stored on a Test Cassette

Perform the following steps to view an individual result stored on a test cassette:

1. From the operator **Main Menu**, highlight **Result History** and press **Select**.



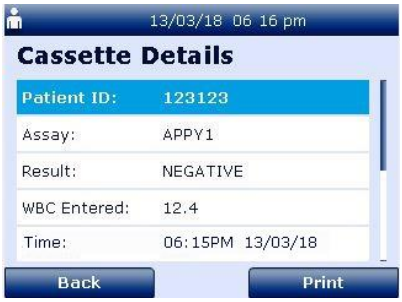
Result History Screen

NOTE: The Result History menu item is not available on the supervisor Main Menu screen. If you are logged in as a supervisor, select Change to Operator.

2. Place the test cassette over the reader keypad**.**

3. Use and to highlight **Read Cassette** and press **Select**.

   The reader displays the patient ID, date, time, and test result for the result stored on the test cassette.



Read Result on Cassette Screen

4. Use and to review the result stored on the cassette:

5. You can also press **Print** to print the result

4.6 Shutdown

To turn off the reader, push the on/off switch until the screen menu disappears, then release it.

5. Review Reader Information

NOTE: Supervisors and operators can review information about the reader. Some information is only available to supervisor users.

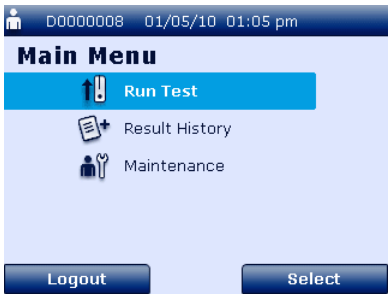
- All users can review the version information for the reader's software. See ***Checking the Software Version*** for instructions.
- All users can review a summary of the reader's settings, including login/logout settings, patient ID settings, and the reader's serial number. See ***Reviewing Global Settings*** for instructions.
- All users can review a listing of actions that have been performed by supervisors. See ***Reviewing the Supervisor History*** for instructions.

5.1 Checking the Software Version

Supervisor users and operator users can review the version information for the reader's software. Perform the following steps to check the software version:

1. Press to display the **Main Menu** screen.

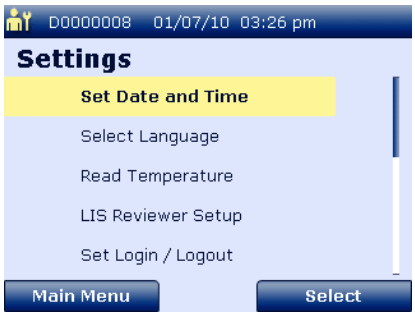
Supervisor Main Menu Screen



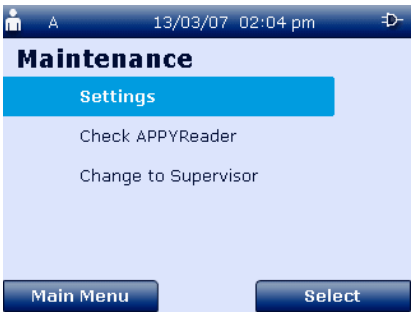
Operator Main Menu Screen

2. *If you are logged in as a supervisor*, use and to highlight **Settings** and press **Select**.

   If you are logged in as an operator, use and to highlight **Maintenance** and press **Select**.



Supervisor Settings Screen

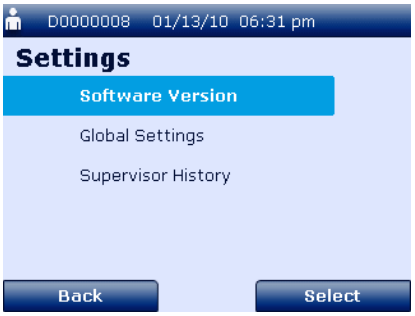


Maintenance Screen

3. *If you are logged in as a supervisor*, use and to highlight **Device Info** and press **Select**.

   If you are logged in as an operator, use and to highlight **Settings** and press **Select**.

Device Info Screen



Operator Settings Screen

4. Use and to highlight **Software Version** and press **Select**.

   The version information for the reader's software is displayed.

Current Software Version Screen

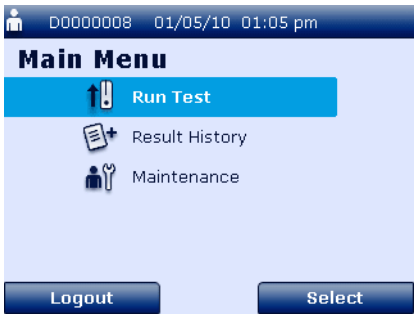
5. Press **Back** to return to the previous screen or press to return to the **Main Menu** screen.

5.2 Reviewing the Supervisor History

Supervisor users and operator users can review a listing of actions that have been performed by supervisors. Perform the following steps to review supervisor history:

1. Press to display the **Main Menu** screen.

Supervisor Main Menu Screen

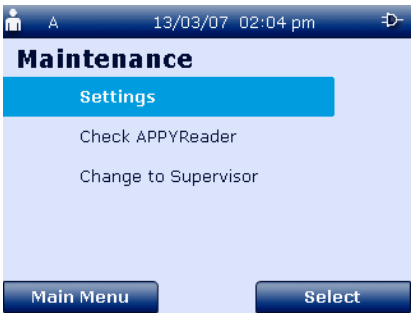


Operator Main Menu Screen

2. *If you are logged in as a supervisor*, use and to highlight **Settings** and press **Select**.

   If you are logged in as an operator, use and to highlight **Maintenance** and press **Select**.

Supervisor Settings Screen

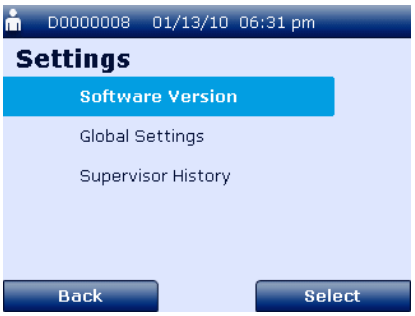


Operator Maintenance Screen

3. *If you are logged in as a supervisor*, use and to highlight **Device Info** and press **Select**.

   If you are logged in as an operator, use and to highlight **Settings** and press **Select**.

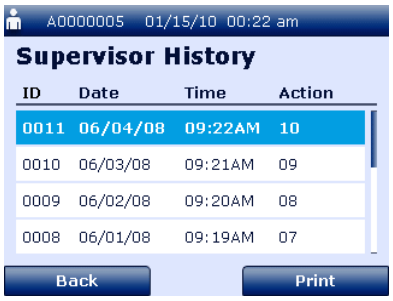
Supervisor Device Info Screen



Operator Settings Screen

4. Use and to highlight **Supervisor History** and press **Select**.

   The reader displays the user ID, date, time, and action identifier for actions that have been performed by supervisor users. You can scroll through actions using and .



Supervisor History Screen

5. If you want to print the supervisor history, press **Print**.

6. Press **Back** to return to the previous screen or press to return to the **Main Menu** screen.

5.3 Reviewing Global Settings

Supervisor users and operator users can review a summary of the following reader settings:

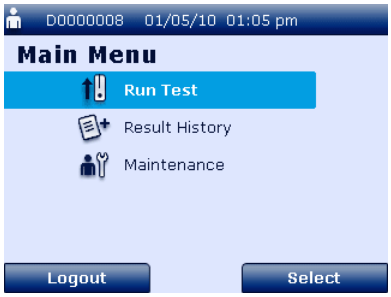
- **Logout Time:** The logout time setting is the duration of inactivity after which a user will be automatically logged out of the reader. To change, see **Changing Security and Power Saving Settings**.
- **APO Time:** The automatic power off time is the duration of inactivity after which the reader will automatically turn off. To change, see **Changing Security and Power Saving Settings**.
- **Auto Login:** The auto-login setting determines whether users are required to enter a login and PIN to use the reader. To change, see Changing **Security and Power Saving Settings**.

- **Immediate Print:** The immediate print setting determines whether test results are printed automatically upon completion of a patient test. To change, see **Changing the Print Setting**.
- **Manual Data Entry:** The manual data entry setting determines whether data can be entered manually. To change, see **Changing Data Entry Method**.
- **Barcode Scanner:** The barcode scanner setting determines whether data can be entered using a barcode scanner. To change, see **Changing Data Entry Method**.
- **Serial Number:** The serial number for the reader is available on this screen.
- **Language:** The language setting determines what language is displayed on the reader screen and printouts. To change, see **Changing the Language**.

Perform the following steps to review global settings:

1. Press to display the **Main Menu** screen.

Supervisor Main Menu Screen

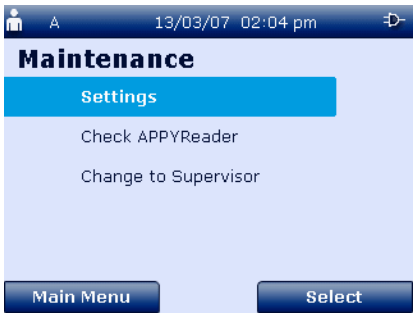


Operator Main Menu Screen

2. *If you are logged in as a supervisor*, use and to highlight **Settings** and press **Select**.

   If you are logged in as an operator, use and to highlight **Maintenance** and press **Select**.

Supervisor Settings Screen

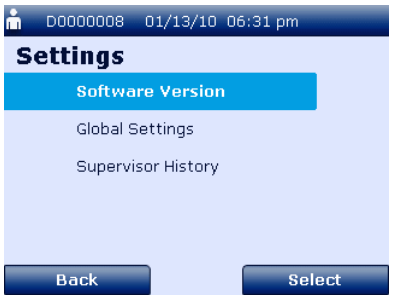


Operator Maintenance Screen

3. *If you are logged in as a supervisor*, use and to highlight **Device Info** and press **Select**.

   If you are logged in as an operator, use and to highlight **Settings** and press **Select**.

Supervisor Device Info Screen



Operator Settings Screen

4. Use and to highlight **Global Settings** and press **Select** to display the **Global Settings** screen.

   The reader's current settings are displayed. You can scroll through settings using and .

Global Settings Screen

5. If you want to print the global settings, press **Print**.

6. Press **Back** to return to the previous screen or press to return to the **Main Menu** screen.

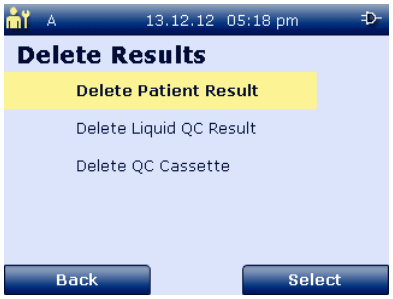
5.4 Deleting Stored Test Results

Supervisor users can delete test results stored in the reader's memory.

IMPORTANT: Test results cannot be retrieved from the reader after they are deleted. Before you delete any test results, make sure that you have archived the results appropriately.

Perform the following steps to delete stored test results:

1. Go to the supervisor **Settings** screen.
2. Use and to highlight **Delete Results** and press **Select**.



Delete Results Screen

3. Select **Delete Patient Result** to delete a patient test.

   The reader displays the patient ID, date, time, and test result for tests in the reader's memory, starting with the most recent test performed.

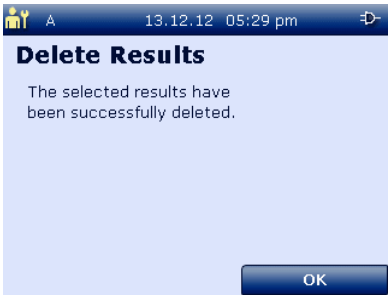
   You can scroll through results using and .

Delete Results Screen

4. Use and to highlight the result you want to delete and press **Options** ▲to display the **Delete Results Options** menu.

Results List Options Screen - Delete Results

5. To delete only the selected result, highlight **Delete Result** and press **Select**
6. To delete all test results, highlight **Delete All** and press **Select**
7. To delete all inconclusive test results, **Delete Inconcl** and press **Select**.
8. To delete all negative test results, highlight **Delete Neg** and press Select
9. After deleting, the reader displays the **Delete Results** confirmation screen to inform you that the selected results have been deleted.



Delete Results Confirmation Screen

10. Press **OK** to return to the **Delete Results** screen or press to return to the supervisor **Main Menu** screen.

6. Maintaining The Reader

Standard maintenance activities for the reader, which can be performed by an operator, include:

- periodically cleaning the exterior of the reader
- changing the paper
- replacing the batteries

Other maintenance activities that might be performed on occasion and can only be performed by a supervisor include:

- changing the date and time
- updating languages available in the reader
- upgrading the reader software

If any other service or maintenance is required, the reader should be sent to the manufacturer. See **Returning the Reader**.

6.1 Cleaning the Reader

The reader requires minimal maintenance. Occasional cleaning of the exterior is usually sufficient. If blood or other fluids are not allowed enough time to fully absorb into test devices, the reader drawer may occasionally require cleaning. Use a damp, not wet, lint-free cloth to apply a 70% ethanol solution on the outside of the reader or to the inside of the reader drawer.

Do not allow water to seep into the printer. Do not immerse the reader in water or other liquids.

If the reader is moved or returned for replacement or repair, the reader should be cleaned prior to transfer.

NOTE: Never insert any tools, swabs, or cleaning materials beyond the open reader drawer.

6.2 Changing the Paper

You can change the paper in the reader anytime. If the reader runs out of paper while in the middle of a printing task and displays the **Empty Paper Tray** message, the paper may be changed and the print job restarted.

To change the paper:

1. Remove the printer cover by pulling up on the blue handle on the top of the cover.

Removing the Printer Cover

2. Remove the empty paper spindle and any unused paper.
3. If necessary, tear or cut the end of the new paper roll to form a straight edge.

   Insert the paper roll into the printer so that the end of the paper comes from under the roll toward the reader display, as shown below.

Inserting the Paper Roll

4. To replace the printer cover, insert the paper roller between the edge of the paper and the paper roll, as shown below.

5. Push down on the sides of the printer cover until you hear it snap into place.

Replacing the Printer Cover

6. Press .

The reader feeds the paper so that it extends out the top of the printer.

6.3 Replacing the Batteries

IMPORTANT: The reader is designed to perform a limited number of tests on a set of new batteries. If you are using batteries, turn the reader off when not in use. You can use the automatic Power Off Time setting to help preserve battery life.

The battery power level is indicated by the icon displayed at the top right of the reader screen. The battery icon is gradually filled with white as the batteries are discharged.

IMPORTANT: Rechargeable batteries are authorized for use with the reader. However, due to the nature of these types of batteries, it is expected they will require recharging more frequently. The reader does not contain a built-in battery charger, and rechargeable batteries must be recharged outside of the reader.

To replace the batteries in the reader:

1. Turn the reader off by pushing the on/off button on the back of the reader, then releasing it.
2. Turn the reader over so that the back of the battery cover is visible.
3. To remove the battery cover, place your thumb in the middle of the cover and exert slight pressure as you slide it in the direction shown below.
4. Remove the old batteries.
5. Insert four size AA 1.5 volt batteries. Be sure that the plus (+) and minus (-) signs on the batteries match the signs embossed in the battery compartment.

Installing the Batteries

6. Replace the battery cover by positioning it at the edge of the battery compartment and sliding it into position.

7. When you have completed battery installation and replaced the battery cover, turn the reader right side up.

IMPORTANT: If the reader does not power on after replacing the batteries, verify that the batteries are lined up according to the symbols in the battery compartment.

7. Troubleshooting Tips

Refer to the table below for instructions for troubleshooting problems.

Problem Condition	Corrective Actions
Paper Jam	1. Remove the printer cover to reveal the paper compartment. 2. Remove and reinsert the paper roll so that the end of the paper comes from under the roll toward the reader display. 3. Replace the printer cover. 4. Press to advance the paper. 5. If the error continues, contact Technical Support for assistance.
Keypad or other keys do not work	Reset the reader by disconnecting the AC power adapter from the reader or removing the four batteries. Wait 30 seconds and reconnect the power adapter or reinsert the batteries.
Reader will not turn on	Ensure that the AC power adapter is connected securely to the reader and to the power outlet or that the four batteries are installed correctly. If the problem continues, connect the AC power adapter to a different power supply or replace the four AA batteries with all new batteries.
Reader is locked up	Reset the reader by disconnecting the AC power adapter from the reader or removing the four batteries. Wait 30 seconds and reconnect the power adapter or reinsert the batteries.
Drawer / test cassette is jammed	***Do not*** pull or force the drawer/test cassette out of the reader. Reset the reader by disconnecting the AC power adapter from the reader or removing the four batteries. Wait 30 seconds and reconnect the power adapter or reinsert the batteries. If you are still unable to open the drawer and/or remove the test cassette, contact Technical Support.

7.1 Understanding Error Messages

Refer to the table below for instructions for responding to error messages.

Error Message	Corrective Action
Barcode Scan Failed	Attempt to read the barcode again. If the problem persists, check the connection to the barcode scanner.
Battery Low	Replace the reader's 4 AA batteries or connect the AC power adapter. Try again to print.
Battery Too Low	Replace the reader's 4 AA batteries or connect the AC power adapter.
Empty Paper Tray	Replace the paper roll in the reader.
Expired Cassette	Remove the expired test cassette and repeat the test with a new test cassette.
ID Already Exists	The selected operator ID is already in use. Enter a different 4-digit operator ID.
Invalid One–Time PIN	The entered PIN is invalid. Try again to enter the one-time PIN that was provided. If the problem persists, contact Technical Support to obtain a new PIN. Each PIN is only valid for 24 hours.
Invalid Patient ID	The patient ID must be 1 to 15 digits. Try again to enter the patient ID.
Invalid Op ID	The operator ID must be 4 numbers. Try again to enter the operator ID.
LAN Error (Cannot Get IP Address)	The DCHP server is not responding with an IP address. Contact your network administrator for assistance.
LAN Error (Network Cannot Be Configured)	The network connection cannot be configured. Contact your network administrator for assistance.
LIS Error (LIS Connection Interrupted)	The connection to the LIS was interrupted. Try the operation again.

Error Message	Corrective Action
LIS Error (LIS Connection Not Available)	The reader failed to connect to the LIS. Try again to establish the connection. If the problem persists, check the network settings or contact your network administrator for assistance.
LIS Error (Reviewer Not Available)	The LIS is currently unavailable. Try again to establish the connection. If the problem persists, contact your network administrator.
Login Failed	The operator ID / PIN combination is invalid. Try again to log in.
Multiple ID Tags Detected	Ensure that only one RFID chip is on or near the reader.
No ID Tag Detected	Place the RFID over the keypad of the reader and try again.
No SD Card Found	Make sure a valid SD card is properly inserted in the reader.
No Upgrade Available	No software upgrade was found on the SD card. Make sure a valid SD card with a software upgrade is properly inserted in the reader.
PIN Mismatch	The confirmed PIN must match the entered PIN.
Printer Temperature High	The printer temperature is too high for printing. Allow the printer to cool off and try again to print.
RFID Error	There was an error during RFID communication. Try again. If the problem persists, move the reader away from possible sources of RF interference.
SD Card Read Error	The SD card may be wrong type or may be damaged. Make sure a valid SD card is properly inserted in the reader.
SD Card Write Error	The SD card may be wrong type or may be damaged. Make sure a valid SD card is properly inserted in the reader.
Temperature Error	The ambient temperature is outside the measurement range of the reader (15°C to 30°C).
Too Many Users Selected	The user database is full. To import more users using the SD card, you must first delete existing users.
Used Cassette	Remove the test cassette and repeat the test with a new cassette.

8. System Specifications

Product Information	
*APPY*Reader Part Number:	**F10009**
Dimensions:	24cm deep x 17cm wide x 12cm high
Weight:	3 lbs.
Power Requirements	
AC Operation:	6 VDC at 4.16 A
Battery Operation:	4 AA / LR6 Cells (Nominal Voltage > 1.5 VDC)
Operating Environment	
Altitude:	0 to 2000m
Temperature:	15°C to 30°C
Humidity:	30% to 80% non-condensing
Storage Environment	
Temperature:	-20°C to 55°C for 24 hours
Humidity:	25% to 85% non-condensing
External Barcode Scanner (optional)	
Connector:	PS/2
Power:	5 VDC < at 300 mA
Codes Supported:	Any 1D code 20 characters or less in length
Model:	Dialogic Touch 65 or equivalent
Network Connectivity (optional)	
Connector:	RJ45
Communications:	10(100)BASE-T using TCP/IP
Data Protocol:	POTC 1-A2

8.1 Returning the Reader

IMPORTANT: Contact your local distributor or Venaxis Technical Support for return authorization instructions.

8.2 Disposing of the Reader

In conformance with the WEEE (Waste Electrical and Electronic Equipment) Directive, do not dispose of this product in municipal waste. Please contact your local distributor to arrange disposal and recycling.

8.3 Accessories and Part Numbers

The following are optional accessories for the reader:

- *APPY*Reader Barcode Scanner (PS/2) REF F10010

9. Glossary

Assay	Test to determine the presence of a substance.
Barcode Scanner	Scanning device that can interpret a barcode - a series of vertical bars of varying widths that each represent a digit from 0 to 9.
Calibration	Process of checking the accuracy of a measuring instrument by comparison of a result to a reference standard.
Internal QC	Quality controls built into the reader's software and / or the test cassette.
Operator	User with operator access privileges, which allows performance of day-to-day operations with the reader.
QC	Quality control. QC refers to steps taken to make sure that a system is of sufficiently high quality.
Reader	The Venaxis *APPY*Reader Instrument used to run the *APPY*1 Test.
Reagent	Chemical substance that is used to create a reaction when combined with another substance for the purpose of analysis.
RFID	Radio frequency identification; a data collection technology that uses electronic tags for storing data and allows automatic identification of items. Unlike barcode technology, RFID provides 'out of line of sight' identification and operates at greater distances than barcode scanners.
SD Card	Secure digital memory card. An SD card is a small flash memory card used for portable storage of digital data that can be imported to and exported from the reader.
Supervisor	User with Supervisor access privileges, which allows performance of advanced reader activities.
Test Cassette	Device containing the necessary reagents that react with the patient sample. Results are measured by the reader to determine the specific chemical substances in the patient.

.

FEDERAL COMMUNICATIONS COMMISSION INTERFERENCE STATEMENT

This instrument complies with Part 15 of the FCC rules. Operations are subject to the following two conditions: (1) this instrument may not cause harmful interference, and (2) this instrument must accept any interference received, including interference that may cause undesired operation.

This instrument has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This instrument generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this instrument does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and the receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult Venaxis or an experienced radio/TV technician for help.

CAUTION:

Any changes or modifications not expressly approved by the grantee of this device could void the user's authority to operate the equipment.

Venaxis, *APPY*1 and *APPY*Reader are trademarks of Venaxis, Inc.

L10019EN-03